

Sorafenib (Nexavar®)

Pronounced: soe-RAF-e-nib

Classification: Multikinase Inhibitor

About Sorafenib (Nexavar®)

Sorafenib is a type of targeted therapy called a multikinase inhibitor. This means it works by targeting receptors specific to the cancer cells, therefore decreasing side effects caused by damage to the healthy cells. A kinase is an enzyme that promotes cell growth. There are many types of kinases, which control different phases of cell growth. Sorafenib actually works by targeting two specific receptors, RAF kinase and VEGF receptors. Blocking the RAF kinase slows down cell division and tumor growth. VEGF receptors are responsible for angiogenesis, or the development of new blood vessels by and for the tumor, so blocking these receptors essentially attacks the tumor's source of nutrients.

How to Take Sorafenib

Sorafenib comes as a tablet to take by mouth. It is usually taken twice a day and should be taken on an empty stomach, 1 hour before or 2 hours after eating. Take sorafenib at around the same times every day. If you miss a dose, skip the missed dose and take the next dose at the scheduled time. Do not try to catch up or double the next dose.

It is important to make sure you are taking the correct amount of medication every time. Before every dose, check that what you are taking matches what you have been prescribed.

The blood levels of this medication can be affected by certain foods and medications, so they should be avoided. These include: warfarin, , carbamazepine, rifampin, phenytoin, St. John's wort, and phenobarbital. Be sure to tell your healthcare provider about all medications and supplements you take.

Storage and Handling

Store your medication in the original, labeled container at room temperature and in a dry location (unless otherwise directed by your healthcare provider or pharmacist). This medication should not be stored in a pillbox. Keep containers out of reach of children and pets.

If a caregiver prepares your dose for you, they should consider wearing gloves or pour the pills directly from their container into the cap, a small cup, or directly into your hand. They should avoid touching the pills. They should always wash their hands before and after giving you the medication. Pregnant or nursing women should not prepare the dose for you. Ask your oncology team where to return any unused medication for disposal. Do not flush down the toilet or throw in the trash.

Where do I get this medication?

Sorafenib is available through select specialty pharmacies. Your oncology team will work with your prescription drug plan to identify an in-network specialty pharmacy for distribution of this medication and shipment directly to your home.

Insurance Information

This medication may be covered under your prescription drug plan. Patient assistance may be available to qualifying individuals without prescription drug coverage. Co-pay cards, which reduce the patient co-pay responsibility for eligible commercially (non-government sponsored) insured patients, are also available. Your care team can help you find these

resources, if they are available.

Possible Side Effects of Sorafenib

There are a number of things you can do to manage the side effects of sorafenib. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

High Blood Pressure

This medication can cause high blood pressure (hypertension). Patients should have their blood pressure weekly during the first 6 weeks of therapy and periodically thereafter. Any hypertension should be treated appropriately. Report any headache or dizziness to your provider.

Fatigue

Fatigue is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

Diarrhea

Your oncology team can recommend medications to relieve diarrhea. Also, try eating low-fiber, bland foods, such as white rice and boiled or baked chicken. Avoid raw fruits, vegetables, whole grain breads, cereals and seeds. Soluble fiber is found in some foods and absorbs fluid, which can help relieve diarrhea. Foods high in soluble fiber include: applesauce, bananas (ripe), canned fruit, orange sections, boiled potatoes, white rice, products made with white flour, oatmeal, cream of rice, cream of wheat, and farina. Drink 8-10 glasses on non-alcoholic, un-caffeinated fluid a day to prevent dehydration.

Decrease in Appetite

Nutrition is an important part of your care. Cancer treatment can affect your appetite and, in some cases, the side effects of treatment can make eating difficult. Ask your oncology care team about nutritional counseling services at your treatment center to help with food choices.

- Try to eat five or six small meals or snacks throughout the day, instead of 3 larger meals.
- If you are not eating enough, nutritional supplements may help.
- You may experience a metallic taste or find that food has no taste at all. You may dislike foods or beverages that you liked before receiving cancer treatment. These symptoms can last for several months or longer after treatment ends.
- Avoid any food that you think smells or tastes bad. If red meat is a problem, eat chicken, turkey, eggs, dairy products and fish without a strong smell. Sometimes cold food has less of an odor.
- Add extra flavor to meat or fish by marinating it in sweet juices, sweet and sour sauce or dressings. Use seasonings like basil, oregano or rosemary to add flavor. Bacon, ham and onion can add flavor to vegetables.

Nausea and/or Vomiting

Talk to your oncology care team so they can prescribe medications to help you manage nausea and vomiting. In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy/fatty, spicy or acidic foods (lemons, tomatoes, oranges). Try saltines, or ginger ale to lessen symptoms.

Call your oncology care team if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

Hand Foot Syndrome

Hand foot syndrome (HFS) is a skin reaction that appears on the palms of the hands and/or the soles of the feet, as a result of certain chemotherapy agents being absorbed by the skin cells. HFS can begin as a mild tingling, numbness, pins-and-needles feeling, redness or pain or swelling of the hands and/or feet. This can then progress to painful swelling, blistering or peeling skin that can interfere with your ability to do normal activities. Be sure to let your oncology team know right away if you notice

these symptoms, as they may need to adjust the chemotherapy dose or take a break to allow the skin to heal. Some tips to help prevent HFS include:

- · Keep hands and feet clean and dry.
- · Avoid tight shoes or socks.
- Avoid activities that put pressure on the palms or soles for 1 week after treatment.
- Apply an alcohol-free moisturizer liberally and often. (Avoid moisturizers with perfumes or scents)
- Avoid very hot water for baths and showers.

Mouth Ulcers (Mucositis)

Certain cancer treatments can cause sores or soreness in your mouth and/or throat. Notify your oncology care team if your mouth, tongue, inside of your cheek or throat becomes white, ulcerated or painful. Performing regular mouth care can help prevent or manage mouth sores. If mouth sores become painful, your doctor or nurse can recommend a pain reliever.

- Brush with a soft-bristle toothbrush or cotton swab twice a day.
- Avoid mouthwashes that contain alcohol. A baking soda and/or salt with warm water mouth rinse (2 level teaspoons of baking soda or 1 level teaspoon of salt in an eight ounce glass of warm water) is recommended 4 times daily.
- If your mouth becomes dry, eat moist foods, drink plenty of fluids (6-8 glasses), and suck on sugarless hard candy.
- Avoid smoking and chewing tobacco, drinking alcoholic beverages and citrus juices

Skin and Nail Changes

Some patients may develop a rash, very dry, or itchy skin. Use an alcohol free moisturizer on your skin and lips; avoid moisturizers with perfumes or scents. Your doctor or nurse can recommend a topical medication if itching is bothersome. Your nails may become dark, brittle or fall off. If your skin does crack or bleed or you lose a nail, be sure to keep the area clean to avoid infection. While receiving this medication, the hair on your head may become curly, fine or brittle. You may experience patchy hair loss or thinning. This tends to resolve once treatment is stopped.

Be sure to notify your healthcare provider of any rash that develops, as this can be a reaction and can become severe. This includes blistering and peeling of your skin or the inside of your mouth. They can give you more tips on caring for your skin, hair and nails.

Less common, but important side effect can include:

- Wound Healing: This medication can lead to slower or incomplete wound healing, such as a surgical wound not healing or staying closed. Be sure to inform the team performing the surgical procedure that you are taking sorafenib. You should also inform your oncology team that a surgical procedure is planned. It is recommended that this medication be discontinued prior to any surgery. In addition, any surgical incision should be fully healed prior to starting or restarting the medication. If you have a surgical wound that has not healed or begins to have signs of infection (redness, swelling, warmth), report this to your healthcare team.
- *Gl Tear:* This medication can cause a tear in the intestinal wall, also called a gastrointestinal perforation. Signs of this can include: new or worsening pain in the abdomen, new abdominal swelling, chills, fever, constipation, nausea or vomiting. If you experience any of these, contact your healthcare provider immediately or go to the emergency room.
- *Heart Rhythm Changes:* This medication can cause slow or abnormal heartbeats or an abnormal heart rhythm called QT prolongation. Notify your oncology care team right away if you feel abnormal heartbeats or if you feel dizzy or faint.
- Bleeding, Stroke, Heart Attack: Sorafenib can increase the risk of blood clots, stroke and heart attack. Symptoms can
 include: swelling, redness or pain in an extremity, chest pain or pressure, pain in your arm, back, neck or jaw, shortness of
 breath, numbness or weakness on one side of the body, trouble talking, confusion or mental status changes. If you
 experience any of these symptoms, you should contact your oncology care team immediately or go to an emergency
 room.
- *TSH Levels in Thyroid Cancer Treatment:* Patients with thyroid cancer may need to have their TSH levels monitored more frequently while on this medication.
- Drug Induced Hepatitis: This medication can cause liver failure, which your oncology care team may monitor for using

blood tests called liver function tests. Notify your healthcare provider if you notice yellowing of the skin or eyes, your urine appears dark or brown, or you have pain in your abdomen, as these can be signs of liver toxicity.

- **Blood Counts:**Your blood counts can be affected by this treatment, though the affect is usually mild. This can cause lower numbers of the following cells:
 - White blood cells (WBC): important for fighting infection. You should let your doctor or nurse know right away if you
 have a fever (temperature greater than 100.4 °F/38 °C), sore throat or cold, shortness of breath, cough, burning with
 urination, or a sore that doesn't heal.
 - Red blood cells: responsible for carrying oxygen to the tissues in your body. You should let your doctor or nurse
 know if you experience any shortness of breath, difficulty breathing or pain in your chest. If the count gets too low,
 you may receive a blood transfusion.
 - Platelets: help your blood clot, so when the count is low you are at a higher risk of bleeding. Let your doctor or nurse know if you have any excess bruising or bleeding, including nose bleeds, bleeding gums or blood in your urine or stool.

Reproductive Concerns

Exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. A woman may need to take a pregnancy test prior to taking this medication. Effective birth control is necessary during treatment and for at least 6 months after treatment for women and 3 months after treatment for men. Even if your menstrual cycle stops or you believe you are not producing sperm, you could still be fertile and conceive. You should not breastfeed for 2 weeks after the end of treatment.

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